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ORIGINAL ARTICLE

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# Eye movement desensitization and reprocessing therapy for psychosis (EMDRp): Protocol of a feasibility randomized controlled trial with early intervention service users

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## Abstract

**Aim:** Traumatic events are involved in the development and maintenance of psychotic symptoms. There are few trials exploring trauma-focused treatments as interventions for psychotic symptoms, especially in individuals with early psychosis. This trial will evaluate the feasibility and acceptability of conducting a definitive trial of Eye Movement Desensitization and Reprocessing for psychosis (EMDRp) in people with early psychosis.

**Methods:** Sixty participants with first episode psychosis and a history of a traumatic/adverse life event(s)will be recruited from early intervention services in the North West of England and randomized to receive16 sessions of EMDRp + Treatment as Usual (TAU) or TAU alone. Participants will be assessed at baseline, 6 and 12 months post-randomization using several measures of psychotic symptoms, trauma symptoms, anxiety, depression, functioning, service-user defined recovery, health economics indicators and quality of life. Two nested qualitative studies to assess participant feedback of therapy and views of professional stakeholders on the implementation of EMDRp into services will also be conducted. The feasibility of a future definitive efficacy and cost-effectiveness evaluation of EMDRp will be tested against several outcomes, including ability to recruit and randomize participants, trial retention at 6- and 12-month follow-up assessments, treatment engagement and treatment fidelity.

**Conclusions:** If it is feasible to deliver a multi-site trial of this intervention, it will be possible to evaluate whether EMDRp represents a beneficial treatment to augment existing evidence-based care of individuals with early psychosis supported by early intervention services.

KEYWORDS

EMDR, feasibility, psychosis, RCT, trauma

## 1 | INTRODUCTION

Psychotic disorders are a major cause of personal and societal burden affecting approximately 0.7% of the population (McManus, Bebbington, Jenkins, & Brugha, 2016; Finberg et al., 2013). They are associated with long-term disability (Wiersma et al., 2000), heightened mortality and risk of suicide (Palmer, Pankratz, & Bostwick, 2005; Saha, Chant, & McGrath, 2007) and reduced recovery outcomes (Jääskeläinen et al., 2013). Recommended pharmacological and psychological interventions (NICE, 2014) can be effective, but response to treatment is modest and variable (e.g., Jauhar et al., 2014; Wykes, Steel, Everitt, & Tarrier, 2008). In addition, patients prescribed antipsychotic medications have relatively low rates of adherence, with approximately only two thirds of medication prescribed actually being taken (Cramer & Rosenheck, 2006). This may be due at least in part to marked and diverse profile of severe side-effects (Young, Taylor, & Lawrie, 2015). Cognitive Behaviour Therapy has consistent but small to moderate effects on positive symptoms only (Bighelli et al., 2018; McKenna, Leucht, Jauhar, Laws, & Bighelli, 2019). Therefore, further work is required in order to improve outcomes.

Approximately 80% of patients with psychosis have a history of traumatic life experiences (de Bont et al., 2015; Hardy et al., 2016). Meta-analyses indicate that trauma is associated with an increased risk of developing psychosis, and heightened severity of psychotic symptoms in those who already have psychosis (e.g., Beards et al., 2013; Varese et al., 2012).The prevalence of trauma and post-traumatic symptoms is particularly marked in individuals with early psychosis (e.g., Rodrigues & Anderson, 2017), possibly due to additional traumatogenic experiences that many people with psychosis are exposed to in the early stages of the illness (e.g., coerced treatment, loss of employment and relationships, the experience of terrifying symptoms). In addition, a range of trauma sequalae, such as dissociation and intrusive memories/flashbacks, are involved in the maintenance of psychotic symptoms (Hardy et al., 2016; Varese, Barkus, & Bentall, 2012; Williams, Bucci, Berry, & Varese, 2018). Clinical guidelines (e.g., NICE, 2014) have recognized both the need for routine trauma assessment in people with first episode psychosis as well as the need for further evaluation of the efficacy and acceptability of trauma-focused therapies for this group.

The treatment of trauma in people with psychosis has largely been ignored until recent years. Psychotic symptoms have been used as an exclusion criterion in 93% of existing trauma-focused intervention trials (Meyer, Farrell, Kemp, Blakey, & Deacon, 2014; Ronconi, Shiner, & Watts, 2014), despite the fact that a substantial minority of patients with psychosis also meet the criteria for Post-Traumatic Stress Disorder (PTSD) and many more report subsyndromal, but nonetheless distressing, trauma symptoms (de Bont et al., 2015). Because of this, there has been recent interest in evaluating trauma-focused therapies in this patient group. Eye Movement Desensitization and Reprocessing (EMDR) is, alongside Trauma-Focused Cognitive Behavioural Therapy (TF-CBT), one of the trauma-focused therapies that has received extensive empirical scrutiny in the last three decades (Bisson et al., 2007; Bisson, Roberts, Andrew, Cooper, & Lewis, 2013). EMDR is endorsed as a recommended intervention for PTSD in several clinical guidelines worldwide (e.g., ISTSS, 2019; NICE, 2018; World Health Organization, 2013) and recent health economic evaluations have attested to its cost-effectiveness relative to other trauma-focused approaches (Mavranezouli et al., 2020). Trials investigating the efficacy of EMDR and other trauma-focused therapies in people with severe mental illness and PTSD have been encouraging (Sin, Spain, Furuta, Murrells, & Norman, 2017). A large-scale RCT in the Netherlands compared the efficacy of EMDR, prolonged exposure (PE) and treatment as usual in individuals with psychosis and comorbid PTSD. Patients receiving PE (56.6%; $p = .006$) or EMDR (60.0%; $p < .001$) were more likely to achieve loss of PTSD diagnosis compared to TAU (27.7%; van den Berg et al., 2015). Both treatments were safe and acceptable, and gains were maintained at 6 months follow-up assessments. Secondary analyses indicated that there were significant reductions in symptoms of psychosis in people who received these interventions (de Bont et al., 2016) but conclusions drawn are limited as the trials were not designed to assess change in psychotic symptoms.

Although EMDR is already being successfully adapted to treat mental health difficulties other than PTSD in people with a trauma history (Novo et al., 2014; Wood & Ricketts, 2013), previous psychosis trials have exclusively evaluated EMDR as a treatment for comorbid PTSD in people with long-standing psychotic disorders. The current trial addresses priorities identified by previous systematic reviews on the application of trauma-focused therapy in people with psychosis (Sin & Spain, 2017; Sin et al., 2017; Swan, Keen, Reynolds, & Onwumere, 2017), in particular (1) whether EMDR can be used safely and effectively in patients with recent onset psychosis and patients with trauma symptoms that do not necessarily meet diagnostic thresholds for PTSD, and (2) whether EMDR can be used to directly ameliorate symptoms of psychosis. Our intervention was adapted from previous work (van den Berg, van der Vleugel, Staring, de Bont, & de Jongh, 2013) and consists of a 16-session manualized EMDR intervention specifically modified to target distressing psychotic symptoms in out-patients with early psychosis. The intervention was developed from pilot work with first episode psychosis clients indicating clinically significant improvements in psychotic symptoms, trauma-related symptoms, anxiety and depression (Ward-Brown et al., 2018). Participants experienced therapy as highly acceptable and helpful, their feedback being used to refine the approach further. The present investigation will examine whether it is feasible to conduct a larger-scale evaluation of "EMDR for psychosis" (EMDRp). The results of this work will be used to inform the design of the future trial, including necessary sample size calculations for a definitive efficacy and cost-effectiveness assessment. It is anticipated that the future trial would focus on the reduction of psychotic symptoms as a primary outcome, with secondary outcomes including trauma symptoms. However, in order to ensure feasibility, a preliminary trial is required before engaging in the large-scale programme.

## 2 | AIMS

To evaluate the feasibility and acceptability of conducting a definitive trial of EMDRp in people with early psychosis. Feasibility will be ascertained across a range of critical parameters, including: recruitment and randomization rate, therapy engagement, assessment

retention and therapy fidelity (see Table 1). Acceptability will be ascertained by qualitative investigations with professionals and service-user participants who have received the EMDRp therapy intervention. Examination of the completeness of outcome measures and variance in outcomes will be used to inform the design and power calculation of a future definitive trial.

## 3 | METHODS

### 3.1 | Design

The EASE trial ("Eye movement desensitization and reprocessing therapy in early psychosis: A feasibility randomized controlled trial", ISRCTN16262847) is a single-blind, parallel group randomized controlled trial with random allocation to one of two arms; EMDRp alongside TAU versus TAU alone. Allocation will be assigned at a ratio of 1:1 and will be concealed from the assessing research assistants (RAs). Participants in both arms will complete assessments at baseline, 6 and 12 months post-randomization. Two qualitative studies will be nested within the trial, one exploring the service user participants' views concerning acceptability and impact of the intervention, and the other exploring the views of professionals regarding implementation of EMDRp within services.

### 3.2 | Participants

The trial will comprise of 60 individuals with first episode psychosis and a history of trauma. Inclusion criteria are listed in Table 2.

The recruitment target was informed by feasibility trials guidelines (Arain, Campbell, Cooper, & Lancaster, 2014; Eldridge et al., 2016; Lancaster, Dodd, & Williamson, 2004) and will enable the

**TABLE 1** Feasibility outcomes of the EASE trial

| Criterion | Critical feasibility outcome | Other feasibility and acceptability data relevant to the criterion | Proposed thresholds on critical outcome |
|---|---|---|---|
| (1) Recruitment rate | Number of participants consented into the trial and randomized | Number of referrals per month<br>Source of recruitment<br>Number of participants contacted,<br>Number of participants assessed for eligibility<br>Reasons for non-eligibility or withdrawal of interest | *Feasibility will be demonstrated where an average of at least three participants are recruited and randomized per month<br>**If at least two participants are recruited per month, then a future trial will be feasible but additional strategies must be identified to support recruitment (e.g., informed by other feasibility data relevant to this criterion)<br>***If an average of one participant is recruited per month over the recruitment period (<20 participants), feasibility within the current design will not be demonstrated |
| (2) Therapy engagement | % who drop-out of therapy/% who did not receive treatment allocated | Session record forms for each therapy session<br>Number of therapy sessions attended<br>Qualitative interviews with SU participants | *Feasibility will be demonstrated if at least 70% of the participants in the intervention arm completed at least 8 out of the 16 sessions of EMDRp<br>**If 50–70% of participants in the intervention arm complete at least 8 out of the 16 sessions of EMDRp<br>***If less than 50% of participants in the intervention arm complete at least 8 out of 16 sessions of EMDRp |
| (3) Assessment retention | % of participants who are lost to follow-up at end-of-treatment and follow-up assessment points | Reasons for withdrawal from the study<br>Qualitative interviews with SU participants | *If at least 70% of participants are retained and the end-of-treatment and follow-up assessments, feasibility will be demonstrated<br>**If 30–70% of participants are retained at the end-of-treatment and follow-up assessments, a future trial will be feasible if strategies to overcome barriers are identified (e.g., via other data relevant to this criterion)<br>***If less than 30% of participants are retained at the end-of-treatment and follow-up assessments, feasibility within the current design will not be demonstrated |
| (4) Therapy fidelity | Adherence ratings from therapy tapes | Session record form for each therapy session (including reasons for deviation from protocol) | *Feasibility will be demonstrated if over 80% of rated therapy tapes will be rated as acceptable<br>**If 50–80% of rated therapy tapes will be rated as acceptable, a future trial will be feasible if strategies to overcome identified barriers (e.g., exploring the reasons for deviation from protocol recorded in the therapist checklists)<br>***If less than 50% of rated therapy tapes will be rates as acceptable, feasibility within the current design will not be demonstrated |

*Note:* * = Continue to main study without modifications—feasible as it is; ** = Continue but modify protocol—the future definitive trial is feasible with modifications. *** = Stop—future definitive trial is not feasible.

**TABLE 2** Participant inclusion and exclusion criteria

| | |
|---|---|
| Inclusion criteria | 1. Aged at least 16 years<br>2. Capacity and willingness to provide informed consent<br>3. **a.** ICD diagnosis of schizophrenia-spectrum disorders (ICD codes F20, F22, F23, F25, F28, F29; ICD-11 codes 6A20, 6A21, 6A23, 6A24, 6A2Y,6A2Z)<br>**b.** or criterion level of positive symptoms severity, indicated by a score > 3 (symptom present) on the delusions (P1), hallucinations (P3), grandiosity (P5) or suspiciousness (P6) items of the PANSS in the previous week<br>**c.** and/or the psychosis transition criteria of the CAARMS<br>4. In contact with mental health services, and have an assigned care-coordinator<br>5. Within 3 years from psychosis onset<br>6. Judged by the assigned care-coordinator/responsible clinician as clinically stable (no treatment change in the previous month, not acutely suicidal and no suicide attempt in the previous 2 months)<br>7. Reporting at least 1 traumatic event on the TSQ, and at least subsyndromal post-traumatic symptoms in the previous week (scores >0 on items 3_1 to 3_5 of the TSQ) |
| Exclusion criteria | Primary diagnosis of substance/alcohol dependence, intellectual disability or cognitive dysfunction, as provided by the participant care-coordinator/clinical team<br>Non-English speaking or requiring an interpreter for the intervention (the therapy and assessment battery at present can only be delivered in English)<br>Receipt of EMDR from a qualified psychological therapist in accordance with NICE guidelines for PTSD (National Institute for Health and Clinical Excellence, 2018) in the past 12 months |

*Note:* Key: CAARMS = Comprehensive Assessment of At-Risk Mental States (Yung et al., 2005); EMDR = Eye Movement Desensitization and Reprocessing Therapy; ICD = the International Classification of Disease; PANSS = Positive and Negative Syndrome Scale (Kay, Fiszbein, & Opler, 1987); TSQ = Trauma Screening Questionnaire (de Bont et al. 2015).

estimation of recruitment and retention parameters as well as the variance of outcome measures. Recruitment will take place across Early Intervention (EI) teams in the North West of England. The trial will be introduced to potential participants by their usual care team. Informed consent will be obtained by trained research assistants (RAs) prior to confirming eligibility via the Trauma Screening Questionnaire and the Positive and Negative Syndrome Scale (Table 2).

### 3.2.1 | Randomization

Participants will be randomly allocated (1:1 ratio) to either EMDRp + TAU, or TAU alone by an unblinded member of the research team (the principal investigator, the trial manager or the trial statistician) using an online pseudo-random list with random permuted blocks of varying sizes. Allocation will be concealed from the RAs conducting assessments.

## 4 | INTERVENTION

EMDR is a trauma-focused therapy in which memories of traumatic experiences are reprocessed to decrease the distress caused by them and change the dysfunctional beliefs and perceptual associations related to the traumatic event. This is achieved through an eight-phase treatment protocol addressing past memories, present triggers and future templates. Treatment phases are outlined in Table 3. Phases do not correspond to specific therapy sessions; multiple phases (usually phases 3–7) can be executed sequentially within the same session. Typically, an EMDR session lasts from 60 to 90 minutes with treatment generally lasting between 8 and 12 sessions. However, more sessions are recommended in the context of complex mental health presentations and severe/multiple trauma histories (NICE, 2018).

The intervention offered in the current trial will be entirely consistent with the eight phases of the standard EMDR protocol but the focus of certain EMDR phases have been modified and expanded (most notably phases 2 and 3, pertaining to client preparation and the assessment and selection of suitable targets for subsequent reprocessing work). This accounts for specific issues related to the experience of psychotic symptoms and their impact on the client's wellbeing. The treatment protocol builds on specific adaptations already suggested in the application of EMDR to the treatment of psychosis (e.g., van den Berg et al., 2013), but represents the first attempt to deliver a manualized intervention that systematically implements these psychosis-specific adaptations. These adaptations involve the inclusion of:

1. a more explicit focus on structure and containment within sessions to safely adhere to the limit of up to 16 sessions provided as part of this feasibility trial. This is achieved through maintaining a clear strand of goal-orientated focus throughout therapy, centring on clients' most distressing present-day challenges and linking this back to and working through related distressing/traumatic experiences, to help progress towards achieving chosen therapeutic goals
2. an enhanced focus on psychoeducation, grounding and client preparation techniques—designed to enable successful reprocessing of traumatic memories including those associated with dissociation (a common concomitant of psychotic experiences; Pilton, Varese, Berry, & Bucci, 2015), concurrent acute psychotic symptoms and related difficulties (e.g., inattention). This may include an enhanced

**TABLE 3** Standard EMDR treatment protocol phases (Shapiro, 2001)

| Phase | Details of EMDR protocol |
|---|---|
| 1 | History Taking (including discussion of the rationale for therapy and case conceptualization/idiographic formulation of the client's difficulties) |
| 2 | Preparation (preparation for reprocessing of target trauma memories and equipping clients with strategies to better self-regulate during trauma reprocessing work) |
| 3 | Assessment (the identification of a specific target memory/image as well as associated negative cognitions, disturbing emotions or bodily sensations; a positive cognition that is preferable to the negative one is also identified) |
| 4 | Desensitization and Reprocessing (involving the repetitive use of bilateral stimulation, for example, the tracking of a moving object, while the client is asked to simultaneously focus on the image, the negative cognition, and the disturbing emotion or body sensation until he/she reports a marked reduction in distress associated with these experiences) |
| 5 | Installation (in which the client is encouraged to associate the trauma memory with the positive cognition previously identified, or a new more adaptive positive cognition) |
| 6 | Body scan (designed to target any residual negative/uncomfortable physical sensation or bodily tension associated with the trauma memory) |
| 7 | Closure (generally involving the use of distress management and tolerance strategies before the end of the session) |
| 8 | Re-evaluation (where the client and therapist re-assess the previous target to evaluate whether additional work is necessary before proceeding further with the intervention) |

preparation phase, using tools such as the Constant Installation of Present Orientation and Safety technique (CIPOS; Luber, 2009) and enhanced practice of EMDR-related resource building and visualization exercises, with a specific focus on psychosis-related challenges or barriers in therapy (such as paranoia and hearing voices)

3. assessment and therapeutic work around trauma symptoms that may not reach diagnostic threshold for PTSD, to familiarize participants with the EMDR approach before targeting more complex trauma memories or psychosis-related traumatic experiences;
4. traumatic experiences that preceded or precipitated the onset of illness (and which may be thematically linked to psychotic symptoms; e.g., Hardy et al., 2005)
5. the traumatic impact of the psychotic episode itself (a source of considerable traumatic stress in many first episode psychosis patients; Berry, Ford, Jellicoe-Jones, & Haddock, 2013; Wilson, Becker, & Tinker, 1997)
6. the impact of adverse life experiences and circumstances that might have exacerbated maladaptive appraisals about psychotic experiences as well as negative beliefs about the self and others that are common in people with psychosis and are associated with distress and impairment in this client group (Garety, Kuipers, Fowler, Freeman, & Bebbington, 2001; Morrison, 2001)

The treatment will be delivered by EMDR therapists who have experience in working with people with psychosis and/or PTSD. All therapists will receive an initial 3-day training workshop in our EMDRp protocol and will attend fortnightly group supervision sessions.

## 4.1 | Treatment fidelity

Using the Modified EMDR Fidelity Checklist (Cooper, Smith, Lewis, Lee, & Leeds, 2019) an EMDR consultant will rate a random selection of therapy recordings (3–5 sessions per therapist) to ensure adherence to EMDR when delivering our protocol. After each therapy session, therapists will also complete a standardized session record form to monitor session content; these will be reviewed during monthly supervision meetings to maximize treatment fidelity throughout the trial.

## 4.2 | Comparator

TAU will be in line with all standard and individually prescribed clinical interventions as directed by clinical guidelines for psychosis (NICE, 2014) and the participants' clinical team, and may include antipsychotic medications and/or psychological interventions. Although EMDR is not routinely employed in the treatment of psychosis, TAU participants with comorbid PTSD may be referred by their clinical teams to other services to receive a trauma-focused interventions (TF-CBT or EMDR). For ethical reasons, the care teams will not be asked to withhold such referrals/interventions. Instead, the care received by TAU participants will be monitored carefully through case notes reviews after the 12-month assessment.

## 4.3 | Outcomes

This trial is designed to evaluate the feasibility of conducting a future definitive trial. Therefore, the data collected at baseline and follow-up assessments are intended to evaluate the feasibility of completing the battery of measures to be employed in the future trial. At both baseline and follow-up assessments, we will administer several measures assessing psychotic symptoms, trauma symptoms, anxiety, depression, functioning, service-user defined recovery as well as quality of life and service usage data to inform future heath economics analyses (Table 4).

**TABLE 4** Summary of measures used to assess participant symptoms across three time points

| Demographic information | | Baseline | 6 months | 12 months |
|---|---|---|---|---|
| Age, sex, ethnicity, employment status and occupation (if relevant), marital status, education level, self-reported diagnosis, time since first episode of psychosis, duration of Early Intervention service input, number and reasons for past psychiatric hospitalizations, current prescribed medications for mental health difficulties (including dosage), diagnosis. | | X | *Updated as required* | |
| **Psychosis-related measures** | | | | |
| **PANSS** | The most widely used research measure to assess the severity of positive and negative symptoms of psychosis as well as symptoms of general psychopathology. | X | X | X |
| **PSYRATS** | A semi-structured interview completed alongside the PANSS to provide a more fine-grained assessment of auditory hallucinations and delusions, including measures of subjective distress caused by these symptoms. | X | X | X |
| **GPTS** | A brief self-report questionnaire assessing paranoid thinking and persecutory delusions. | X | X | X |
| **VIS** | A questionnaire assessing a range of positive and negative consequences of voices (i.e., auditory verbal hallucinations) on various domains | X | X | X |
| **QPR** | A service user-defined measure of subjective recovery from psychosis. | X | X | X |
| **Trauma-related measures** | | | | |
| **TSQ** | A brief measure used to screen for trauma exposure and post-traumatic stress symptoms. In the present study, the modified version of the TSQ developed by de Bont et al. (2015) for use in people with psychosis will be used to check the participants' potential eligibility in this trial | X | | |
| **TALE** | A measure specifically designed to assess exposure to adverse and traumatic life experiences that are commonly reported by people with psychosis. | X | | |
| **PCL-5** | A self-report questionnaire assessing the presence and severity of post-traumatic symptoms. | X | X | X |
| **ITQ** | A brief measure assessing the severity of symptoms of PTSD and complex PTSD as defined in the recently published ICD-11. | X | X | X |
| **DES-II** | A self-report measure of dissociation. | X | X | X |
| **Health economic measures** | | | | |
| **EQ-5D-5L** | A health status questionnaires used in health economics analyses. | X | X | X |
| **EPQ** | An adapted version of the EPQ for specific use in early intervention for psychosis services. | X | X | X |
| **Other mental health and functioning measures** | | | | |
| **GAD-7** | A brief and widely used questionnaires assessing symptoms of anxiety. | X | X | X |
| **PHQ-9** | A brief and widely used questionnaires assessing symptoms of depression. | X | X | X |
| **PSP** | A scale assessing patients' functioning in four areas (socially useful activities, personal and social relationships, self-care and disturbing/aggressive behaviours). | X | X | X |
| **QPR** | A service user-defined measure of subjective recovery from psychosis. | X | X | X |

*Note:* Key: DES-II = The Dissociative Experiences Scale-II (Carlson & Putnam, 1993); EPQ = Economic Patient Questionnaire (Davies et al., 2007); EQ-5D-5L = The EuroQol 5-Dimension 5-Level measure (Janssen et al., 2013); GAD-7 = The Generalized Anxiety Disorder Questionnaire (Spitzer, Kroenke, Williams, & Löwe, 2006); GPTS = Green Paranoid Thoughts Scale (Green et al., 2008); ITQ = International Trauma Questionnaire (Cloitre et al., 2018); PANSS = Positive and Negative Syndrome Scale (Kay et al., 1987); PCL-5 = The PTSD Checklist for DSM-5 (Blevins, Weathers, Davis, Witte, & Domino, 2015); PHQ-9 = The Patient Health Questionnaire (Kroenke, Spitzer, & Williams, 2001); PSP = The Personal and Social Performance Scale (Morosini, Magliano, Brambilla, Ugolini, & Pioli, 2000); PSYRATS = The Psychotic Symptoms Rating Scales (Haddock, McCarron, Tarrier, & Faragher, 1999); QPR = The Questionnaire about the Process of Recovery (Neil et al., 2009); TALE = The Trauma and Life Events checklist (Carr, Hardy, & Fornells-Ambrojo, 2018); TSQ = The Trauma Screening Questionnaire (de Bont et al., 2015); VIS = The Voices Impact Scale (Strauss, n.d.).

## 5 | ANALYSIS

Descriptive statistics will be used to summarize assessments of feasibility and acceptability in terms of the primary outcomes (Table 1). Further descriptive information on the flow of participants across the trial will be provided in accordance with relevant CONSORT fields for feasibility trials (Eldridge et al., 2016). These will include: (1) number of referrals received per month, (2) source of recruitment, (3) number of participants contacted, (4) number of participants assessed for eligibility, (5) number of participants consented into the trial and

randomized, (6) reasons for non-eligibility or withdrawal of interest, (7) retention of participants between baseline, end-of-treatment and follow-up assessment periods, discriminating between participants who did not receive the treatment allocated and individuals lost to follow-up, (8) all important harms or unintended effects, and (9) the completeness of participant's responses on all self-reports. Data on all self-report and researcher-administered outcome measures will be examined for completeness. No formal hypothesis testing will be carried out comparing the two groups for clinical effectiveness. However, outcome measures will be summarized by arm and standard deviations will be estimated to inform the design of a future trial. Estimation of the integrity of the intervention will rely on descriptive analyses of the EMDR fidelity checklists and data from therapy session record forms. This will inform training and supervision provision of the future definitive trial.

### 5.1 | Qualitative studies

One month following their 6-month post-randomization (end of treatment) assessment, participants in the EMDRp + TAU arm will be invited to complete a qualitative interview. Consistent with previous work (Awenat et al., 2017), we will use purposive sampling to recruit a wide range of participants, based upon demographics and therapy experiences (e.g., by recruiting participants with poor vs. good treatment response). Semi-structured interviews conducted a researcher unblinded to treatment allocation will be audio-recorded and transcribed. Inductive Thematic Analysis (Braun & Clarke, 2013) will be used to extract themes relating to experiences of participating in the trial and undergoing EMDRp.

Also consistent with previous work (Awenat et al., 2017), we will also recruit approximately 20 professionals (dependent upon theoretical sufficiency) whose role would impact either on participant referral to the trial ('gatekeepers') and the commissioning, service/treatment delivery and/or management of psychological therapies for psychosis. Purposive sampling will facilitate recruitment of wide range of professional backgrounds from across healthcare organizations and relevant services (e.g., commissioners; therapy services managers; EI care coordinators, clinical psychologists and psychiatrists). These interviews will cover questions relevant to the future implementation of EMDRp, including their stakeholders' views on their understanding, views and concerns about EMDR and the perceived barriers to implementing EMDRp in EI services, alongside solutions to such barriers/problems. All interviews will be audio recorded, transcribed verbatim and analyzed using inductive thematic analysis.

## 6 | DISCUSSION

The impact of trauma and the management of trauma-related symptoms in people with psychosis is a recognized research priority (NICE, 2014). The overarching aim of this trial is to determine the feasibility of running a definitive trial of EMDRp within EI services. The delivery of such trials is vital to improving outcomes for those affected by early psychosis and trauma. The application of trauma-focused therapies to the treatment of psychosisis in its infancy. However, based on extensive evidence linking trauma sequelae to psychotic symptoms (Williams et al., 2018), it is possible that EMDRp may have direct effects on psychotic symptoms. Our feasibility data will allow evaluation of the likely levels of recruitment and retention into a future larger-scale trial. The project will also enable the evaluation of the acceptability of EMDRp by considering levels of therapy engagement, the qualitative feedback from participants allocated to receive EMDRp, and the extent to which EMDR therapists can deliver our EMDRp protocol with high level of fidelity.

Several trials have recently been conducted to evaluate the efficacy of trauma-focused therapy in people with psychotic disorders (e.g., Brand, McEnery, Rossell, Bendall, & Thomas, 2018). The present trial is distinguished in that the primary focus is the evaluation of a treatment protocol aimed at improving psychotic symptoms rather than co-morbid PTSD. Although previous trials have predominantly focused on participants who have been living with psychosis for many years (e.g., van den Berg et al., 2015), our trial specifically considers individuals with early psychosis who receive support from EI services. Access to effective treatment in the first few years following the onset of psychosis is a crucial determinant of future clinical and functional outcomes (Bird et al., 2010). The findings of our trial and the future definitive evaluation informed by the present trial will confirm whether trauma-focused therapies could augment existing evidence-based treatment options for early psychosis, and should, therefore, be offered routinely to clients supported by EI services. Our EMDRp intervention was developed from previous clinical recommendations for adapting the delivery of EMDR to people with distressing psychosis (van den Berg et al., 2013) and with input from 'experts-by-experience' who took part in case studies of trauma-focused therapy in early psychosis conducted by members of our team (Ward-Brown et al., 2018; Ward-Brown & Keane, 2019). A further strength is that the design of the trial has been developed in collaboration between academic researchers, frontline trauma therapists and experts-by-experience, hopefully ensuring the development of a “real-world”, practical and effective intervention which improves outcomes for those affected by psychosis and experiences of trauma and could be implemented in future clinical practice in a sustainable and effective way.

There are several limitations to the study. First, our feasibility trial does not have an active control treatment arm, so our findings will be silent regarding the potential effectiveness of EMDRp relative to other psychosocial interventions with an established evidence-base for the treatment of psychosis, or other trauma-focused therapies. Second, this early stage evaluation is unlikely to shed light on the mechanisms of action of EMDR when applied to the treatment of trauma-related difficulties reported by people with psychosis. Both limitations could be addressed in the future definitive trial through the selection of evidence-based psychosocial comparators (e.g., Cognitive Behavioural Therapy for psychosis; NICE, 2014) and the integration of research methods to evaluate mechanisms of efficacy of complex

mental health interventions (e.g., Dunn et al., 2015), a line of research that could be informed by the growing evidence on the potential mediators of the trauma-psychosis relationship (Williams et al., 2018) and the neural and psychological mechanisms of action of EMDR in other patient groups (e.g., Landin-Romero, Moreno-Alcazar, Pagani, & Amann, 2018).

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## CONFLICT OF INTEREST

Co-authors Logie, Keane, and Malkin are involved in the delivery of EMDR training workshops and events. All other co-authors have no conflicts of interest to declare.

## DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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